K000220

FEB 24 2000

510(k) Summary

Premarket Notification [510(k)] summary prepared on January 18, 2000.

Establishment Information

Manufacturer/Summiteer:	Motion Lab Systems, Inc. 4326 Pine Park Drive, Baton Rouge, LA 70809
Contact Name/Phone #	Edmund Cramp Motion Lab Systems, Inc. Phone: (225) 928-4248 Fax: (225) 928-0261

General Device Information

Common/Usual Name	EMG System
Trade/Proprietary Name	MLS MA-300 system
Classification Name	Electromyography, Diagnostic - 21 CFR 890.1375
Device Classification	Class II
Performance Standards	None established under section 514

Substantial Equivalence:

The MLS MA-300 Electromyographic System is substantially equivalent to the Vicon EMG system, 510(k) number K853804.

Device Description:

The purpose of the MLS MA-300 Electromyographic System is to amplify myoelectric and other signals generated during subject activity.

Intended Use:

The MLS MA-300 Electromyographic System enables researchers and clinicians to acquire EMG and other related signals from active subjects. It is intended to be used in hospital, university and other research facilities to acquire information for display and analysis by, or under the direction of, a health care professional.

Testing:

Data collected by the predicate system and the proposed MLS MA-300 Electromyographic System were compared to determine substantial equivalence and relative performance. Myographic recordings from the skin surface over a single muscle were found to be substantially identical in frequency content and power spectrum for both devices.

510(k) Summary

Comparison to legally marketed predicate device:

Characteristic	Vicon EMG system 510(k) K853804	Proposed MLS device
Intended Use	Ambulatory myoelectric EMG monitoring.	Ambulatory myoelectric EMG monitoring.
Power Source	AC Line Voltage	AC Line Voltage
CMRR	95 dB	98 dB minimum
System Input Impedance	Greater than 100 MΩ	Greater than 100 MΩ
Power requirements	< 50 Watt	< 50 Watt
Signal Bandwidth	20 Hz to 2,300 Hz	20 to 2,000 Hz -3dB

Conclusion:

Testing done on the MLS MA-300 Electromyographic System and the predicate system indicates the proposed MLS MA-300 Electromyographic System is as safe and effective and performs a substantially equivalent function to the predicate system.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 24 2000

Mr. Edmund Cramp
President
Motion Lab Systems, Inc
4326 Pine Park Drive
Baton Rouge, Louisiana 70809

Re: K000220
Trade Name: MA-300 Electromyographic system
Regulatory Class: II
Product Code: IKN
Dated: January 19, 2000
Received: January 24, 2000

Dear Mr. Cramp:

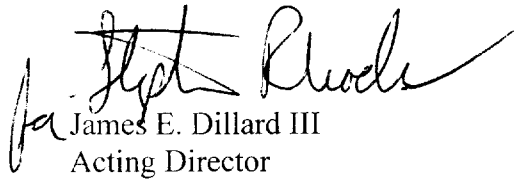
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,



James E. Dillard III
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K000220

Device Name: **MLS Electromyographic system**

Indications for Use:

The MLS Electromyographic system enables researchers and clinicians to acquire EMG signals from active subjects. It is intended to be used in hospital, university and other research facilities to acquire EMG signals for display and analysis by, or under the direction of, a health care professional.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K000220

Prescription Use X OR Over-The-Counter Use_____
(Per 21 CFR 801.109)